

K 041184

JUN 23 2000

CP Medical

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PO BOX 6724 Portland, OR 97208,

TEL. (503) 232-1555, Fax (503) 230-9993
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510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1999 and 21 CFR 807.92."

Applicant: C.P. Medical
836 N.E. 24th
Portland, OR 97232
Tele: (503) 232-1555
Fax: (503) 230-9993

Contact Patrick J. Ferguson (President)
or
Thomas R. Brammer (V.P. Manufacturing)

Date: February 5, 2000

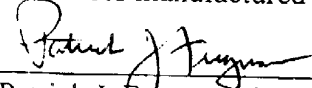
Name of Device:
Common or Usual Name: Silk Nonabsorbable Surgical Suture
Classification Name: Suture, Nonabsorbable, Silk

Silk Nonabsorbable Surgical Sutures USP, manufactures by C. P. Medical, are equivalent to the Silk Nonabsorbable Surgical Sutures, USP, manufactured by USSC / Davis & Geck.

The Silk Nonabsorbable Surgical Suture USP manufactured by C. P. Medical and USSC Davis & Geck are braided and coated with silicone. The C. P Medical Silk Surgical Suture is dyed Black (Logwood) or Undyed. USSC / Davis & Geck's Silk Surgical Suture is dyed Black (Logwood) or Undyed.

The Silk Nonabsorbable Surgical Sutures USP are indicated for use in general soft tissue approximation and/or ligation included use in Cardiovascular, Ophthalmic and Neurological procedures.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods described in USP 24 demonstrates that C. P. Medical Silk Nonabsorbable Surgical Suture meet or exceed USP specifications and are equivalent in terms of the above parameters to Silk Nonabsorbable Surgical Sutures manufactured by USSC / Davis & Geck.


Patrick J. Ferguson, President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 23 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Patrick Ferguson
President
CP Medical
836 N.E. 24th Avenue
Portland, Oregon 97232

Re: K001184
Trade Name: Silk Nonabsorbable Surgical Suture
Regulatory Class: II
Product Code: GAP
Dated: April 11, 2000
Received: April 11, 2000

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Tuesday, October 26, 1993 (Vol. 58, No. 205, Pages 57557 and 57558).

A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Silk Nonabsorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
2. This device may not be manufactured from any material other than multifilamentous fibers composed of fibroin, an organic protein that is derived from the domesticated species *Bombyx mori* (B. mori) of the family Bombycidae. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Silk Nonabsorbable Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

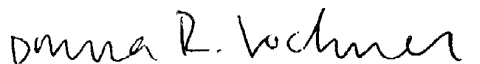
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, The Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control Provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597, or at its internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number if known K001184

Device Name Silk Nonabsorbable Surgical Suture

Indication for Use:

General soft tissue approximation and/or ligation including use in Cardiovascular, Ophthalmic and Neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001184

Prescription Use: X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 00-00-00)